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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,536	02/26/2004	Arthur M. Krieg	C1039.70083US05	9640

7590 11/17/2009

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,536	KRIEG ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,39-45 and 47-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,39-45 and 47-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed June 30, 2009 is acknowledged and has been entered. Claims 1-36, 38 and 46 have been canceled. Claims 37 and 54 has been amended. Claims 37, 39-45, 47-56 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

2. It is noted that pending claims 37, 39-45, 47-56 have been examined.

3. It is noted that a mew matter rejection is being set forth in this Action with regard to the amendment to claims filed February 25, 2008. The Examiner regrets any inconvenience.

4. The amendment filed February 25, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

A method for stimulating a subject's response to a vaccine comprising an administering an immunostimulatory oligonucleotide adjuvant as a vaccine adjuvant with the vaccine to the subject to stimulate the stimulate the subject's response to the vaccine, wherein the immunostimulatory oligonucleotide comprises a phosphate backbone modification and greater than two unmethylated cytosine-guanine dinucleotides, and wherein the oligonucleotide is at least eight nucleotide in length and a 5'TC dinucleotide.

The specification does not disclose the claimed composition as set forth above. Neither the specification nor the sequence listing discloses an immunostimulatory oligonucleotide that has a "phosphate backbone modification and greater than two unmethylated cytosine-guanine dinucleotides, and wherein the oligonucleotide is at least eight nucleotide in length and a 5'TC dinucleotide". There is no support in the specification or claims for the recitation of "greater than two unmethylated cytosine-guanine dinucleotides". The specification's sequence listing has

immunostimulatory nucleic acids that are at least 8 nucleotides in length and have greater than two unmethylated cytosine-guanine dinucleotides or immunostimulatory nucleic acids that are 8 nucleotides or greater in length and include a 5'TC dinucleotide. However, there are no immunostimulatory oligonucleotides that have all of the claimed limitations and characteristics: "phosphate backbone modification and greater than two unmethylated cytosine-guanine dinucleotides, and wherein the oligonucleotide is at least eight nucleotide in length and a 5'TC dinucleotide". It is noted that two unmethylated cytosine-guanine dinucleotides is not the same as "greater than two unmethylated cytosine-guanine dinucleotides". The Examiner interprets this phrase to mean three or more unmethylated cytosine-guanine dinucleotides.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 37, 39-44 and 47-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A method for stimulating a subject's response to a vaccine comprising an administering an immunostimulatory oligonucleotide adjuvant as a vaccine adjuvant with the vaccine to the subject to stimulate the stimulate the subject's response to the vaccine, wherein the immunostimulatory oligonucleotide comprises a phosphate backbone modification and greater than two unmethylated cytosine-guanine dinucleotides, and wherein the oligonucleotide is at least eight nucleotide in length and a 5'TC dinucleotide.

The specification does not disclose the claimed composition as set forth above. The specification nor the sequence listing discloses an immunostimulatory oligonucleotide that has a "phosphate backbone modification and greater than two unmethylated cytosine-guanine

dinucleotides, and wherein the oligonucleotide is at least eight nucleotide in length and a 5'TC dinucleotide". There is no support in the specification or claims for the recitation of "greater than two unmethylated cytosine-guanine dinucleotides". The specification's sequence listing has immunostimulatory oligonucleotides that are at least 8 nucleotides in length and have greater than two unmethylated cytosine-guanine dinucleotides or immunostimulatory oligonucleotides that are 8 nucleotides or greater in length and include a 5'TC dinucleotide. However, there are no immunostimulatory oligonucleotides that have all of the claimed limitations and characteristics: "phosphate backbone modification and greater than two unmethylated cytosine-guanine dinucleotides, and wherein the oligonucleotide is at least eight nucleotide in length and a 5'TC dinucleotide". It is noted that two unmethylated cytosine-guanine dinucleotides is not the same as "greater than two unmethylated cytosine-guanine dinucleotides". The Examiner interprets this phrase to mean three or more unmethylated cytosine-guanine dinucleotides. [0046] of the specification does not specifically teach greater than two methylated cytosine-guanine dinucleotides. The recitation of "...the magnitude of this stimulation typically could be increased by adding more CpG dinucleotides..."([0046]) This does not teach or suggest an immunostimulatory oligonucleotide having "greater than the two unmethylated cytosine-guanine dinucleotides. Further, none of the sequences set forth in Table 1meet all of the criteria set forth in claim 37 for an immunostimulatory oligonucleotide.

The specification does not disclose the claimed composition as set forth above. The specification nor the sequence listing discloses an immunostimulatory oligonucleotide that has the properties as set forth in item 3. The specification's sequence listing has immunostimulatory oligonucleotides that are at lest 8 nucleotides in length and have greater than two unmethylated cytosine-guanine dinucleotides (see for example SEQ ID NO: 8, 11, 15) or immunostimulatory oligonucleotides that are at least 8 nucleotides in length and include a 5'TC dinucleotide (see for example SEQ ID NO: 21-26). The specification does not enable the claimed invention.

None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to

"make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry,, whatever is now claimed. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991).

Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of compositions, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 45 and 54-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 50 of copending Application No. 11/127797. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim method of inducing (stimulating) the immune response of a subject to a vaccine comprising the vaccine and immunostimulatory oligonucleotide (unmethylated CpG, at least 8 nucleotides in length and has a phosphate backbone modification) and administering the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The rejection is maintained for the reasons of record. Applicant's arguments filed June 30, 2009 have been fully considered but they are not persuasive. Applicants have asserted that the rejection is a provisional one since claim 45 in the 11/127,797 application has not been found allowable. If the cited claim is found allowable, Applicants will address the rejection. It

is noted that this rejection will be maintained until the instant application is found to be in condition for allowance or the claims amended to overcome the rejection.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. Minnifield/
Primary Examiner, Art Unit 1645
November 8, 2009